

APR - 5 2004

510(k) Summary

K032797

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Submitter: Hoya Conbio (formerly Continuum)
47733 Fremont Blvd
Fremont, CA 94538

Contact: Tom Haney
VP Dental Products

Date Summary Prepared: September 4, 2003

Device Trade Name: DELight dental laser system

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser
79-GEX

Equivalent Device(s): WaterLase, Millennium dental laser system

Intended Use: Cutting, shaving, contouring and resection of oral osseous tissues (bone).

Comparison: The BioLase WaterLase, Millennium dental laser systems are equivalent in operating parameters, physical characteristics, and intended uses.

Nonclinical Performance Data: None

Clinical Performance Data: None

Additional Information: None

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas Haney
Vice President, Dental Products
Hoya Conbio
47733 Fremont Boulevard
Fremont, California 94538

Re: K032797

Trade/Device Name: DELight Dental Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 29, 2003
Received: January 6, 2004

Dear Mr. Haney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

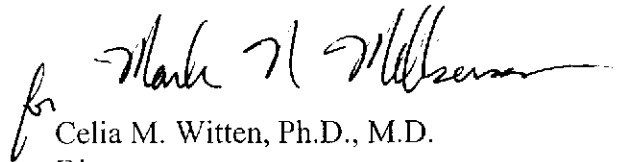
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K032797

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Indications for Use Statement

510(k) Number (if known): *pending*

Device Name: DELight Dental Laser System

Indications for Use: Cutting, shaving, contouring and resection of oral osseous tissues (bone)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K032797

Prescription Use X
(Per 21 CFR 801.109)

OR Over-the-Counter Use _____

(Optional Format 1-2-96)

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